REMARKS

I. Interview Summary

Applicants thank Examiners Holt and Pak for granting Applicants a telephonic interview on September 10, 2008. Compliant with M.P.E.P. § 713.04, Applicants hereby provide the following summary of the interview. The cited prior art documents of Shell (U.S. Patent No. 5,972,389) and Wong (U.S. Patent No. 6,120,803) forming the basis of the art rejections set forth in the April 15, 2008 Office Action were discussed.

II. Status of the Claims

Claims 1-20, and 22-26 are pending. Claim 21 has been cancelled. With this amendment, claims 1, 8, and 22 are amended. New claims 27-29 have been added. The amendments of the claims and the various rejections raised in the Office Action are discussed in more detail, below.

III. Amendments

Claim 1 is amended to recite a matrix/active agent tablet dosage form. Support for this amendment is found, for example, on page 36, paragraph [0132] of the originally filed specification. Claim 1 is further amended to recite the dosage form maintains its size for an extended period of time before it is diminished by erosion. Support for this amendment is found, for example, on page 18 paragraph [0063]

Support for new claims 27-28 is found, for example, in original claim 1.

Support for new claim 29 is found, for example, in claim 17.

Claim 8 is amended to depend from new claim 27, and claim 22 is amended to depend from new claim 28.

Accordingly, the claim amendments do not introduce new matter.

IV. Double-Patenting Rejection

Claims 1, 5, and 11-13 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 17, 21 and 23 of Application Serial No. 10/773,986. Claims 18-20 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 52 and 65-66 of pending Application Serial No. 10/281,284. The Examiner noted that a timely filed Terminal Disclaimer in compliance with 36 C.F.R. §1.321(c) would overcome an actual or provisional rejection on this ground.

Applicants respectfully request the rejection be held in abeyance until allowable subject matter is achieved, at which time Applicants will file a terminal disclaimer if necessary.

V. Rejections Under 35 U.S.C. § 102

Claims 1-10 and 22-26 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Shell *et al.*, U.S. Patent No. 5,972,389 (herein "Shell").

Claims 1-3 and 22-24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Wong *et al.*, U.S. Patent No. 6,120,803 (herein "Wong").

These rejections are respectfully traversed for the following reasons.

A. The Present Claims

The present claims are directed to a method of delivering a pharmacologically active agent, comprising orally administering to the patient, a matrix/active agent tablet dosage form. The matrix/active agent tablet dosage form comprises a polymer matrix and a pharmacologically active agent dispersed in the polymer matrix. The polymer matrix is comprised of a biocompatible, hydrophilic polymer. The dosage form, upon imbibition of water, swells unrestrained dimensionally to a size effective to promote gastric retention, and maintains its size for an extended period of time before it is diminished by erosion.

B. The Applied Art

SHELL relates to a dosage form for delivery of sparingly soluble drugs comprising a plurality of solid particles. The dosage form, as taught by Shell, rapidly dissolves or

disintegrates upon contact with water and/or gastric fluid to permit the particles to quickly disperse in the stomach (column 2, lines 9-14).

WONG relates to a gastric retentive dosage form comprised of a polymer matrix surrounded by a solid band of insoluble material that completely prevents the affected portion of the dosage form from achieving any swelling.

Wong fails to teach or suggest a method of delivering an agent comprising a gastric retentive dosage form that swells unrestrained dimensionally.

C. Analysis

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

1. All of the elements of the claims are not taught by Shell

The Examiner asserts that Shell disclose a sustained-release drug dosage form for delivering a pharmacologically active agent, the drug dosage form comprising a plurality of solid particles or pellets of a solid-state drug dispersed within a polymer that (i) swells unrestrained dimensionally via imbibition of gastric fluid to increase the size of the particles to promote gastric retention, (ii) gradually erodes over a time period of hours, with the erosion commencing upon contact with the gastric fluid, and (iii) releases the drug to the stomach and duodenum at a rate dependent on the erosion rate (Office Action mailed April 15, 2008, first half of page 7).

As stated above, the present claims are directed, in part, to a method of delivering a pharmaceutically active agent comprising administering a matrix/active agent tablet dosage form that upon imbibition of water swells unrestrained dimensionally to a size effective to promote gastric retention, *and maintains its size for an extended period of time before it is diminished by erosion.*

Thus, the dosage form as now recited in Applicants' claims is in stark contrast to the dosage form taught by Shell. Specifically, the dosage form of Shell that is administered to a patient is comprised of a plurality of particles, which are specifically designed to rapidly fall apart upon administration. When the Shell dosage form is administered to a patient, for example, in the form of a tablet or a capsule, the dosage form rapidly dissolves or

disintegrates, as intended, upon contact with the gastric fluid to permit the particles to quickly disperse in the stomach (see, for example, column 2, lines 9-14). Thus, Shell fails to teach or suggest a method of administering a dosage form that maintains its size for an extended period of time before it is diminished by erosion.

2. The elements of Applicants' claims are not taught by Wong

The Examiner asserts that Wong discloses an active agent dosage form that is retained in the stomach and useful for the prolonged delivery of an active agent formulation to a fluid environment for use. The Examiner further states that the dosage form disclosed by Wong is a polymer matrix that swells upon contact with the fluid of the stomach.

Applicants disagree. As stated above, the present claims are directed to a method for delivering a pharmacologically active agent, comprising administering a dosage form that swells unrestrained dimensionally to a size effective to promote gastric retention. In contrast, the approach taught by Wong is specifically designed to *constrain swelling of the dosage form* by securing a swelling-preventing insoluble band surrounding the tablet.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102.

VI. Rejections Under 35 U.S.C. § 103

Claims 1-3, 11-14 and 18-20 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Shell, U.S. Patent No. 5,972,389, in view of Louie-Helm et al., Proceedings for Controlled Release Society, 2001 (herein, "Louie-Helm") and Cipro® Drug Information Sheet (2000). This rejection is respectfully traversed for the following reasons.

A. The Present Claims

The Present Claims are described above with reference to the anticipation rejection.

B. The Applied Art

Shell is summarized above with reference to the anticipation rejection.

Louie-Helm *et al.* relate to the pharmacokinetics of gastric retentive tablets of ciprofloxacin hydrochloride.

The Cipro® Drug Information Sheet teaches ciprofloxacin hydrochloride as a synthetic broad spectrum antimicrobial agent for oral administration.

C. Analysis

The rejection is traversed as the cited references, either alone or in combination, fail to describe or suggest Applicants' claimed invention.

C1. The scope and content of the combined teachings of Shell in view of Louie-Helm and the Cipro® Drug Information Sheet differs from the claimed subject matter.

The Examiner asserts that it would be obvious to combine the teachings of the three cited references to achieve a method of delivering a pharmacologically active agent, ciprofloxacin, in a controlled or sustained release formulation by combining the ciprofloxacin active ingredient with a biocompatible, hydrophilic polymer that upon imbibition of water swells unrestrained to promote gastric retention (Office Action dated April 15, 2008, page 13, second paragraph). The Examiner states that Shell teach a dosage form comprising a plurality of solid particles or pellets of a solid-state drug dispersed within a polymer that swells unrestrained dimensionally via imbibition of gastric fluid to increase the size of the particles to promote gastric retention within the stomach of a patient in which the fed mode has been induced. The Examiner further cites Louie-Helm as teaching oral administration of gastric retentive tablets of ciprofloxacin hydrochloride, and that the tablets are administered with food and swell to a size sufficient to be retained in the stomach in the fed mode. The Examiner also cites the Cipro® Drug Information Sheets as teaching ciprofloxacin as a synthetic broad spectrum antimicrobial agent for oral administration. Applicants respectfully disagree that the combined teachings of Shell, Louie-Helm and the Cipro® Drug Information Sheet teach or suggest the claimed methods.

The present claims recite methods of administering a gastric retentive dosage form that upon imbibition of water, swells unrestrained dimensionally to a size effective to promote gastric retention, and maintains its size for an extended period of time before it is diminished by erosion.

As stated above, the dosage form of Shell is specifically designed to *not* maintain any integrity upon imbibition of gastric fluid or water. This specific property is critical to design of the dosage form to release the plurality of particles as rapidly as possible to an environment of use (see, for example, column 2, lines 9-14). Thus, Shell fails to teach or suggest a method of administering a dosage form that maintains its size for an extended period of time before it is diminished by erosion. In fact, Shell teaches away from the embodiment as claimed by Applicants.

The Examiner further relies on Louie-Helm for teaching gastric retentive dosage forms that contain ciprofloxacin hydrochloride. Neither Louie-Helm nor the Cipro® Drug Information Sheet teach or purport to describe a method of administering a gastric retentive dosage form that maintains its size for an extended period of time before it is diminished by erosion.

Accordingly, the combined teachings of Shell, Louie-Helm and the Cipro® Drug Information Sheet fail to teach or suggest Applicants claimed invention.

Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

VII. Conclusion

For the reasons above, Applicants respectfully submit that the pending claims are novel and non-obvious over the cited art. Furthermore, Applicants respectfully submit that all criteria for patentability have been satisfied and the pending claims are in full condition for allowance. A Notice of Allowance is therefore respectfully requested.

No fees are believed due with this communication. However, the Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No.:50-4616.

If the Examiner has any questions or believes a telephone conference would expedite the prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 590-1919.

Respectfully submitted,

Date: October 15, 2008

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